K103512

510(k) Summary

JAN 7 2011

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.87 (b)

Product Name: Affirm Breast Biopsy Guidance System

Product Classification Name: Mammographic X-Ray System

Product Classification Code: 90 IZH **CFR Section:** 892.1710

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36-37 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Gail Yaeker-Daunis
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Date Prepared: November 28, 2010

Predicate Device: K071542, Hologic Digital StereoLoc II

Device Description:

The Affirm Breast Biopsy Guidance System used with the Selenia Dimensions 2D Full Field Digital Mammography System (FFDM), is a stereotactic lesion localization system that has the application of localizing, and then giving a physician the capability of performing fine needle aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination.

Stereotactic images on the host mammography system are acquired at +/-15°. The stereo images are calculated with Cartesian coordinates to target lesions. Stereo images are displayed on the mammography system display for the targeting procedure. Images are then sent to PACS for archiving via DICOM protocol.

Safety Features include:

- Automatic detection of mounting, latching, and connection of biopsy module

- C-arm motion disabled if biopsy module is not locked in place
- Automatic compression release disabled when biopsy module installed
- Motorized movement of biopsy device only under user control
- Audible alert if biopsy device motion could result in mechanical interference

Indications for Use:

The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions 2D Full Field Digital Mammography System. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

Comparison with Predicate Devices:

The Hologic Affirm Breast Biopsy Guidance System is substantially equivalent to **K071542 Hologic Digital StereoLoc II,** which is used with the Selenia Full Field Digital Mammography X-ray system to provide location of areas of concern and pre-surgical localization for performance of breast biopsies on an upright mammography system.

Summary of Testing

The Hologic Affirm Breast Biopsy Guidance System was successfully tested by UL to IEC 60601-1 Medical Electrical Equipment Standards. Stereotactic images captured, saved and/or transmitted by the Selenia Dimensions 2D FFDM conform with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Hologic successfully performed design control verification and validation tests in accordance with 21 CFR Part 820.

Conclusion

The Affirm Breast Biopsy Guidance System design, operation, construction and materials are similar to existing marketed device with no additional risks or hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 7 2011

Ms. Gail Yaeker-Daunis
Senior Regulatory Specialist
Hologic, Inc.
36-37 Apple Ridge Road
DANBURY CT 06810

Re: K103512
Trade/Device Name: Affirm Breast Biopsy Guidance System
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: November 29, 2010
Received: November 30, 2010

Dear Ms. Yaeker-Daunis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Premarket Notification: Affirm Breast Biopsy Guidance System

510(k) No. K103512

Device Name: Affirm Breast Biopsy Guidance System

Indications For Use

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)

Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K 103512